22. (Amended) A method according to Claim 21, wherein the piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof is minoxidil or a minoxidil salt.

23. (Amended) A method according to Claim 22, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

REMARKS

Applicants' undersigned representative wishes to thank Examiners Dees and Gollamudi for their time and helpful suggestions in the telephone interview held on January 25, 2002, during which the pending claims and prior art were discussed. Reconsideration in view of the above amendments and following remarks is respectfully requested.

By virtue of this response, claims 1, 3-5, 9, 11, 17-19 and 21-23 have been amended, and claim 25 has been cancelled.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, and Applicants reserve the right to prosecute the subject matter of such claims in continuation and/or divisional applications.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the Specification

An abstract has now been provided, in accordance with 37 C.F.R. § 1.72(b).

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-20 and 25 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

In particular, claim 1 has been rejected as being indefinite in the recitation of the phrases "a pharmaceutically active composition including as the pharmaceutically active component" and "a solvent composition including a solvent." Applicants believe claim 1 is definite, in that the "pharmaceutically active component" refers to the claimed piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof, and the "solvent composition" refers to a combination of the claimed solvent and co-solvent. Nevertheless, Applicants have amended claim 1 to remove the phraseology "pharmaceutically active component" and "solvent composition", further clarifying that the claimed pharmaceutically active composition comprises, inter alia, a piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof, a solvent, and a co-solvent. Claims 3-5, 9, 11, 17, 18, 21 and 22 have been similarly amended for consistency in terminology with amended claim 1.

Claim 19, as well as claim 23, have been amended to clarify that the recited minoxidil salts are specifically minoxidil acetetate or minoxidil lactate.

Applicants stress that the foregoing amendments merely provide further clarification of the claimed subject matter, but are not believed to alter the scope of the claims, i.e., the amendments do not narrow the scope of the claims.

Claim 25 has been cancelled, rendering the rejection as to this claim moot.

Based on the foregoing, Applicants believe claims 1-20 satisfy the requirements of 35 U.S.C. § 112, second paragraph, and request withdrawal of the rejection.

Rejection under 35 U.S.C. § 102

Claims 1-9, 12-16, 18-19, 21-23 and 25 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Yu et al. (US 5,571,841). Applicants respectfully traverse the rejection.

Compositions according to the present invention have several advantages, including providing greater concentrations of a piperidinopyrimidine derivative, such as minoxidil, without the necessity of utilizing large amounts of propylene glycol. In some cases propylene glycol can be excluded altogether. (See, e.g., page 2, lines 15-23.) Yu et al., on the other hand, is directed

to the use of hydroxyacids to enhance the "therapeutic efficacy of cosmetic and pharmaceutical agents." (column 2, lines 16-21.) Yu et al. clearly does not disclose or suggest the claimed formulation of claim 1, which specifically requires "at least 5% by weight" of a "piperdinopyrimidine derivative or a pharmaceutically acceptable salt thereof" and propylene glycol, if even present at all, in an amount of "less than approximately 10% by weight."

In making the rejection, the Examiner states the "prior art [Yu et al.] reads on all instant amounts," citing specifically to Example 3 and column 6, line 44 through column 7, line 16. Example 3 of Yu et al. describes a "2% minoxidil" formulation formed by dissolving 2 grams minoxidil and 3 ml lactic acid into a mixture of 80 ml ethanol and 15 ml propylene glycol. This 2% minoxidil formulation is a far cry from the claim 1 composition which requires 5% or greater of a piperidinopyrimidine derivative, such as minoxidil. In addition, the formulation of Example 3, with its large propylene glycol content, results in a formulation having substantially greater than the "less than approximately 10% by weight" of propylene glycol required by claim 1. As can be seen then, the formulation exemplified in Example 3 of Yu et al. does not teach or suggest the particular composition of claim 1.

The disclosure at column 6, line 44 through column 7, line 16, of Yu et al. likewise does not teach or suggest the particular composition of claim 1. This section discusses generally desired concentration ranges of hydroxyacids and cosmetic and pharmaceutical agents, as well as various pharmaceutically acceptable vehicles, without specifying any particular formulations of such hydroxyacids, agents and vehicles. Certainly, nothing in this section can be construed as teaching or suggesting the recited composition of claim 1, which specifically requires 5% or greater of a piperidinopyrimidine derivative, such as minoxidil, by weight, and propylene glycol, when present, at less than approximately 10% by weight.

Based on the above, Applicants respectfully submit claim 1 is patentable over Yu et al., as are claims 2-9, 12-16, 18-19 depending therefrom, and request withdrawal of the rejection as to these claims.

Claim 21 is directed to a method for the treatment of hair loss and related indications, the claimed method including the step of providing a pharmaceutical composition which is primarily as recited in claim 1. As discussed, Yu et al. does not teach or suggest the composition of claim 1 and therefore cannot be considered to teach or suggest a method of using such a composition. Applicants submit method claim 21, as well as claims 22 and 23 depending therefrom, are thus likewise patentable over Yu et al. and request withdrawal of the rejection as to these claims.

Claim 25 has been cancelled, rendering the rejection as to this claim moot.

Rejection under 35 U.S.C. § 103

Claims 10, 11, 17, 20 and 24 have been rejected under 35 U.S.C. § 103 as being unpatentable over Yu et al. in view of Uchikawa et al. (US 5,156,836). Applicants respectfully traverse the rejection.

Uchikawa et al. is directed to hair revitalizing tonics containing amine oxide. The reference is specifically relied upon as teaching the use of benzyl alcohol as a solvent and certain ratios of water/ethanol mixtures.

The deficiencies of Yu et al. with respect to the claimed invention have been discussed above. Putting aside the issue of whether one skilled in the art would indeed be motivated to combine Yu et al. with Uchikawa et al., the addition of the benzyl alcohol or the water/ethanol mixtures of Uchikawa to the formulations of Yu et al., still would not achieve or suggest the claimed composition containing 5% or greater of a piperidinopyramidine derivative, such as minoxidil, by weight, and propylene glycol, when present, at less than approximately 10% by weight. Neither would such a combination teach or suggest a method of using such a composition.

Applicants therefore submit claims 10, 11, 17, 20 and 24 are patentable over Yu et al. in view of Uchikawa et al. and request withdrawal of the rejection.

CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would further expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 468452000400.

Respectfully submitted,

Dated: February 20, 2002 By: Cameron A King

Cameron A. King
Registration No. 41,897

Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: (415) 268-6524
Facsimile: (415) 268-7522

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Amended) A pharmaceutical composition for topical administration comprising: [, including, as the pharmaceutically active component,]

at least 5% by weight, based on the total weight of the composition, of a piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;

an acid in an amount to substantially completely solubilise the piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;

[a solvent composition including] a solvent selected from water and/or a lower alcohol; and

a co-solvent selected from one or more of the group consisting of aromatic and polyhydric alcohols; wherein when the co-solvent includes propylene glycol, it is present in an amount of less than approximately 10% by weight.

3. (Amended) A pharmaceutical composition according to Claim 1, wherein the piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof [pharmaceutically active component] is present in an amount of from approximately 5 to 25% by weight, based on the total weight of the pharmaceutical composition.

4. (Amended) A pharmaceutical composition according to Claim 3, wherein the piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof [pharmaceutically active component] is present in an amount of approximately 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

5. (Amended) A pharmaceutical composition according to Claim 1, wherein the piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof [pharmaceutically active component] is minoxidil or a salt thereof.

9. (Amended) A pharmaceutical composition according to Claim 1, wherein the [solvent] composition includes water and ethanol in a range of approximately 1:1 to 1:3 by volume.

11. (Amended) A pharmaceutical composition according to Claim 1, wherein the [solvent] composition [system] includes water and benzyl alcohol wherein the benzyl alcohol is in an amount of approximately 40 to 100% by weight based on the total weight of the co-solvent system.

17. (Amended) A pharmaceutical composition according to Claim 1, wherein the composition [solvent system] includes water and ethanol in a range of approximately 9:1 to 1:9 by volume.

18. (Amended) A pharmaceutical composition according to Claim 5, wherein the piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof [pharmaceutically active component] is a minoxidil salt.

19. (Amended) A pharmaceutical composition according to Claim 18, wherein the minoxidil salt is [a] minoxidil acetate or minoxidil lactate [salt].

21. (Amended) A method for the treatment of hair loss and related indications in humans, comprising the steps of: [which method includes]

providing a pharmaceutical composition for topical administration having [, including, as the pharmaceutically active component,]

at least 5% by weight, based on the total weight of the composition, of a piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;

an acid in an amount to substantially completely solubilise the piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;

[a solvent composition including] a solvent selected from water and/or a lower alcohol; and

a co-solvent selected from one or more of the group consisting of aromatic and polyhydric alcohols; wherein when the co-solvent includes propylene glycol, it is present in an amount of less than approximately 10% by weight; and

applying topically to the human scalp a therapeutically or prophylactically effective amount of the pharmaceutical composition.

22. (Amended) A method according to Claim 21, wherein the piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof is [pharmaceutically active component includes] minoxidil or a minoxidil salt.

23. (Amended) A method according to Claim 22, wherein the minoxidil salt is [a] minoxidil acetate or minoxidil lactate [salt].